Automedx, Inc.'s SAVe – Simplified Automated Ventilator
510(k) Summary (K071221)

Contact:
James Evans
President & CEO
12321 Middlebrook Rd Ste 150
Germantown, Md 20874
(301) 916-9508

Submission Date: May 1, 2007

Manufacturer:
Automedx, Incorporated
12321 Middlebrook Rd. Ste 150
Germantown, MD 20874
P: (301) 916-9508
F: (301) 916-7155

Classification Name
Ventilator, Emergency, Powered, (Resuscitator)

Regulation Number
868.5925

Predicate Device
Impact Uni-Vent 754 (K931473)

Intended Use / Indications for Use

The SAVe is intended for use on adults that need ventilatory support. Specifically, the SAVe is intended to provide short term ventilatory support for individuals during CPR or when positive-pressure ventilation is required to manage acute respiratory failure. The SAVe device is appropriate for individuals that weigh at least 45 kilograms. It is intended to be used in field hospitals, transport and pre-hospital environments.

Technological Characteristics

The SAVe is a time cycled ventilator that delivers a set tidal volume. If, at any point, an upper threshold pressure is reached, the device immediately triggers the exhale mode.

The SAVe consists of an internal pump (blower), rechargeable sealed lead acid battery, circuit board, manifold, face plate, EMI shielded upper and lower enclosure, air intake port with debris filter, patient

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port, pressure port, supplemental air / oxygen port, electric port for recharging and / or running, charger / power supply, patient circuit, pressure tubing, oxygen tubing and an activation switch.

The device has audio and visual alarms that trigger for low pressure, disconnect, blockage, low battery, high temperature or internal failure. The device not only alarms for stacked breaths but also cuts off the pump until adequate pressure has been released before triggering the next breath.

The SAVe comes in three distinct models. Each has a set tidal volume and respiratory rate. Model 550x10 delivers 550 mL of air 10 times per minute. Model 600x10 delivers 600 mL of air 10 times per minute and Model 600x12 delivers 600 mL of air 12 times per minute.

Performance Data

The SAVe was thoroughly tested as per all applicable parts of the FDA's Draft Reviewer Guidance for Ventilators dated July 1995. Its performance vis-à-vis the Impact Uni-Vent 754 showed substantial equivalence to the predicate device. The results of that test can be found in **Appendix I.** In addition to the bench tests performed, external tests were conducted by third parties to see if the SAVe met various standards for electromagnetic compatibility and air quality. In all instances, the SAVe functioned as intended and all observed results were as expected.

Substantial Equivalence

The SAVe has a fixed tidal volume and respiratory rate that are a subset of the capabilities of the Uni-Vent 754. At these settings, the SAVe is as safe and effective as the Uni-Vent 754. The SAVe's intended use and indications for use are also a subset of the predicate device. Both devices use similar technological characteristics and principles of operation. The minor technological differences between the SAVe and its predicate device raise no new issues of safety or effectiveness. Bench generated performance data demonstrate that the SAVe is as safe and effective as the Uni-Vent 754 at the prescribed settings. Thus, the SAVe is substantially equivalent to the Uni-Vent 754.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2007

Mr. James D. Evans
President and Chief Executive Officer
Automedx, Incorporated
12321 Middlebrook Road, Suite 150
Germantown, Maryland 20874

Re: K071221
Trade/Device Name: Simplified Automated Ventilator – SAVe
(Models 550x10, 600x10, 600x12)
Regulation Number: 21 CFR 868.5925
Regulation Name: Powered Emergency Ventilator
Regulatory Class: II
Product Code: BTL
Dated: August 29, 2007
Received: August 29, 2007

Dear Mr. Evans:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

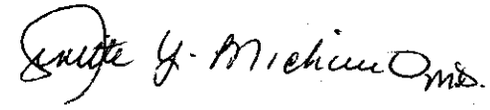
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K071221

Device Name: **Simplified Automated Ventilator** - SAVe (Models 550x10, 600x10, 600x12)

The SAVe is intended for use on adults that need ventilatory support. Specifically, the SAVe is intended to provide short term ventilatory support for individuals during CPR or when positive-pressure ventilation is required to manage acute respiratory failure. The SAVe device is appropriate for individuals that weigh at least 45 kilograms. It is intended to be used in field hospitals, transport and pre-hospital environments.

Prescription Use _X_ (Part 21 C.F.R. 801 Subpart D) AND/OR Over-The-Counter Use____ (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anita G. Michaels MD.

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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